IN THE UNITED STATES PATENT	AND TRADEMARK OFFICE
In re application of: Scherrmann et al.  Serial No.: Not Yet Assigned  Filed: January 9, 2002  For: Cocaethylene Immunogens and Antibodies	) Examiner: Not Yet Assigned ) Art Unit: Not Yet Assigned ) PRELIMINARY AMENDMENT )
BOX PATENT APPLICATION Assistant Commissioner of Patents PO Box 2327 Arlington, VA 22202	
Sir:	
Prior to examination of the above-referenced respectfully requested to make the amendments show Show Changes Made".	
AMEND	MENTS
In the Specification	
On page 1, line 1 insert the following section	titled "CROSS-REFERENCE TO
RELATED APPLICATIONS"	
This application is a continuation of USSN	09/477,269, filed January 4, 2000, which is a

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I hereby certify under 37 C F R  $\,$  1 10 that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" with sufficient postage on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, PO Box 2327, Arlington, VA 22202

#### Jean-Michael Scherrmann et al.

Serial No. Not Yet Assigned

continuation of USSN 09/139,536, filed August 25, 1998, which issued September 5, 2000, as USPN 6,114,508, which is a continuation of USSN 08/821,895, filed March 21, 1997, which issued November 6, 1998, as USPN 5,817,770, which disclosures are incorporated herein by reference.--

#### In the Claims

Pursuant to 37 CFR §1.121, amendments made to the claim 6 and 7 and new claims 13-25 are shown on separately attached "Clean Copy of the Pending Claims". Also attached is a "Version with Markings to Show Changes Made to the Claims".

#### REMARKS

## In the Claims:

New claims 13-26 were added. Claims 1-12 were cancelled.

Claims 13-25 were added. Support for new claim 13 is found on p. 6 lines 28-31 and p. 7 lines 1-4. Support for new claim 14 is found on page 3 lines 4, 9-16, page 6 lines 28-31, page 7 lines 1-4 and on page 4 lines 4-21. Support for new claim 15 is found on page 3 lines 3-4, page 4 lines 4-23, page 5 lines 1-14 and page 7 lines 1-4. Support for new claim 16 is found on page 6 lines 1-6 and page 7 lines 8-10. Support for new claim 17 is found on page 7 lines 1-4. Support for new claim 18 is found on page 6 lines 1-6 and 28-31 and page 7 lines 1-4 and lines 8-10. Support for new claim 19 is found on page 4 line 25. Support for new claim 20 is found on page 4 lines 25-26. Support for new claim 21 is found on page 4 line 26. Support for new claim 22 is found on page 7 lines 1-4. Support for new claim 23 is found on page 6 line 4. Support for new claim 24 is found on page 7 lines 16-18. Support for new claim 25 is found on page 6 lines 1-6 and page 7 lines 1-6.

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## **CONCLUSION**

Applicants believe no new matter has been introduced by these amendments and the Examiner is respectfully requested to enter the amendments. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (650) 328-4400.

Respectfully submitted,

Date: \/9-02

Koren J. Anderson, Ph.D.

Reg. No. P-51,061

Rae-Venter Law Group, P.C. P.O. Box 60039 Palo Alto, CA 94306

Telephone: (650) 328-4400 Facsimile: (650) 328-4477

BRV/KJA

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Scherrmann et al.  Serial No.: Not Yet Assigned  Filed: January 9, 2002  For: Cocaethylene immunogens and antibodies	) Examiner: Not Yet Assigned ) Art Unit: Not Yet Assigned ) VERSION WITH MARKINGS TO SHOW CHANGES
BOX PATENT APPLICATION Assistant Commissioner for Patents PO BOX 2327 Arlington, VA 22202	. )
Sir:  The Examiner is respectfully requested to ma of the text of the claims is attached hereto (See, "Cle	
In the Claims:	

Cancel Claims 1-12

Add the following new Claims.

--13. (New) A composition comprising:

a hybridoma cell culture producing monoclonal antibodies which bind specifically to cocaine and cocaethylene and have low or no cross reactivity with benzoyl ecgonine.

(Printed Name)

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Sout fatting
(Signature)
Robert Pattison

- 14. (New) The hybridoma cell line according to Claim 13, wherein said cell line is produced from a host immunized with an immunogen comprising at least one cocaethylene hapten conjugated to an antigenic protein, wherein said cocaethylene hapten comprises N-methyl tropane substituted at the 2-position with a carboxyethyl group and at the 3-position with a benzoyloxy group, wherein the benzyoyloxy group is substituted at the para position with an aliphatic linking group of from 1-6 atoms, and said linking group comprises carbon atoms and 0 to 2 heterotaoms, said heteroatoms consisting of oxygen and nitrogen, wherein said aliphatic linking group terminating in said antigenic protein.
- 15. (New) The hybridoma cell line according to Claim 13, wherein said cell line is produced from a host immunized with an immunogen comprising at least one cocaethylene hapten conjugated to an antigenic protein, wherein said cocaethylene hapten comprises N-methyl tropane substituted at the 2-position by carboxyethyl or N-ethylcarboxamnide and at the 3-position by benzoyloxy or benzamido, wherein bonded at the para position of said benzoyloxyl or benzamido is a linking group or a carboxy group is attached to said linking group, wherein at least one of the substituents has an amido group, and wherein said bonding to the antigenic protein is through said carboxyl group.
- 16. (New) A monoclonal antibody produced by a hybridoma cell according to any one of Claims 13 to 15
- 17. (New) A hybridoma cell line produced by fusing spleen cells from a host immunized with an immunogen according to Claim 15 with immortalized host B cells, wherein said hybridoma cell line produces a monoclonal antibody which reacts with cocaine and cocaethylene and has low or no cross reactivity with benzoyl ecgonine.
- 18. (New) The hybridoma cell line according to Claim 17, wherein said antigenic protein is

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bovine serum albumin.

- 19. (New) The hybridoma cell line according to Claim 17, wherein said antigenic protein is keyhole limpet hemocyanin.
- 20. (New) The hybridoma cell line according to Claim 17, wherein said antigenic protein is tetanus toxoid.
- 21. (New) A monoclonal antibody produced by a hybridoma cell line according to any one of Claims 17-20.
- 22. (New) A monoclonal antibody according to Claim 21, wherein said monoclonal antibody is classified IgG, or equivalent thereof.
- 23. (New) A monoclonal antibody, which binds specifically to cocaine and cocaethylene and has low or no cross reactivity to benzoyl ecgonine.
- 24. (New) A monoclonal antibody according to Claim 23, labeled with an agent capable of providing a detectable signal.
- 25. (New) A monoclonal antibody according to Claim 23, wherein said monoclonal antibody has an affinity of at least 5 X 10<sup>8</sup> for cocaine and cocaethylene and a comparatively low affinity for benzoyl ecgonine, wherein said monoclonal antibody is classified as IgG, or equivalent thereof.
- 26. (New) A composition comprising a monoclonal antibody according to Claim 23.--

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Respectfully submitted,

Koren J. Anderson, Ph.D.

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#### **PATENT**

## ATTORNEY DOCKET NO. DASI.002.03US

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Scherrmann et al.	)
	) Examiner: Not Yet Assigned
Serial No.: Not Yet Assigned	)
	) Art Unit: Not Yet Assigned
Filed: January 9, 2002	)
	) <b>CLEAN COPY OF CLAIMS</b>
For: Cocaethylene immunogens and antibodies	)
	)
	)
BOX PATENT APPLICATION	
Assistant Commissioner for Patents	
PO BOX 2327	

Sir:

The following is a clean copy of the claims with the amendments as shown on the attached "Version with Markings to Show Changes Made".

# In the Claims:

Arlington, VA 22202

- 13. (New) A composition comprising:
  a hybridoma cell culture producing monoclonal antibodies which bind specifically to cocaine and cocaethylene and have low or no cross reactivity with benzoyl ecgonine.
- 14. (New) The hybridoma cell line according to Claim 13, wherein said cell line is produced from a host immunized with an immunogen comprising at least one cocaethylene hapten

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(Printed Name)

conjugated to an antigenic protein, wherein said cocaethylene hapten comprises N-methyl tropane substituted at the 2-position with a carboxyethyl group and at the 3-position with a benzoyloxy group, wherein the benzyoyloxy group is substituted at the para position with an aliphatic linking group of from 1-6 atoms, and said linking group comprises carbon atoms and 0 to 2 heterotaoms, said heteroatoms consisting of oxygen and nitrogen, wherein said aliphatic linking group terminating in said antigenic protein.

- 15. (New) The hybridoma cell line according to Claim 13, wherein said cell line is produced from a host immunized with an immunogen comprising at least one cocaethylene hapten conjugated to an antigenic protein, wherein said cocaethylene hapten comprises N-methyl tropane substituted at the 2-position by carboxyethyl or N-ethylcarboxamnide and at the 3-position by benzoyloxy or benzamido, wherein bonded at the para position of said benzoyloxyl or benzamido is a linking group or a carboxy group is attached to said linking group, wherein at least one of the substituents has an amido group, and wherein said bonding to the antigenic protein is through said carboxyl group.
- 16. (New) A monoclonal antibody produced by a hybridoma cell according to any one of Claims 13 to 15
- 17. (New) A hybridoma cell line produced by fusing spleen cells from a host immunized with an immunogen according to Claim 15 with immortalized host B cells, wherein said hybridoma cell line produces a monoclonal antibody which reacts with cocaine and cocaethylene and has low or no cross reactivity with benzoyl ecgonine.
- 18. (New) The hybridoma cell line according to Claim 17, wherein said antigenic protein is bovine serum albumin.
- 19. (New) The hybridoma cell line according to Claim 17, wherein said antigenic protein is

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keyhole limpet hemocyanin.

- 20. (New) The hybridoma cell line according to Claim 17, wherein said antigenic protein is tetanus toxoid.
- 21. (New) A monoclonal antibody produced by a hybridoma cell line according to any one of Claims 17-20.
- 22. (New) A monoclonal antibody according to Claim 21, wherein said monoclonal antibody is classified IgG, or equivalent thereof.
- 23. (New) A monoclonal antibody, which binds specifically to cocaine and cocaethylene and has low or no cross reactivity to benzoyl ecgonine.
- 24. (New) A monoclonal antibody according to Claim 23, labeled with an agent capable of providing a detectable signal.
- 25. (New) A monoclonal antibody according to Claim 23, wherein said monoclonal antibody has an affinity of at least 5 X 10<sup>8</sup> for cocaine and cocaethylene and a comparatively low affinity for benzoyl ecgonine, wherein said monoclonal antibody is classified as IgG, or equivalent thereof.
- 26. (New) A composition comprising a monoclonal antibody according to Claim 23.

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